JUL 1 9 2000

K000944

16. 510(k) Safety Summary

A. Name of Device

Trade Name: Thermage ThermaCool System

Common Name: Electrosurgical Unit and Accessories

Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)

B. Predicate Devices

Device	Premarket Notification
Radionics Cool-Tip RF System	K984552, 03/05/99
ArthroCare Visage Cosmetic Surgery System	K981870, 08/20/98
Candela Dynamic Cooling Device	K981033, 08/15/96

C. Device Description:

The Thermage ThermaCool System consists of the following components.

- RF Generator
- Handpiece Connection Module
- Cooling Module
- Handpiece Assembly (consisting of Handpiece and RF Electrode Insert), and
- Accessory cables and tubing.

The Handpiece Assembly connects to the distal end of the Handpiece Connection Module and to the distal end of the Cooling Module. The proximal end of the Handpiece Connection Module and the proximal end of the Cooling Module connect to the RF Generator.

The Thermage ThermaCool System is monopolar. Commercially available dispersive electrodes (return pads) are required for operation.

D. Indicated Use

The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool System are substantially equivalent to those of the Radionics Cool-Tip RF System, as well as the ArthroCare Visage Cosmetic Surgery System, and the Candela Dynamic Cooling Device.

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool System is substantially equivalent to devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Mr. Keith Mullowney
President
Thermage, Inc.
4058 Point Eden Way
Hayward, California 94545

Re: K000944
Trade Name: ThermaCool System
Regulatory Class: II
Product Code: GEI
Dated: May 30, 2000
Received: June 1, 2000

Dear Mr. Mullowney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K000944

DEVICE NAME: Thermage ThermaCool System

INDICATIONS FOR USE:

The Thermage ThermaCool System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vachon

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000944

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)